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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,884	12/21/2001	Alan Williams	3441	2317

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/028,884

Applicant(s)

WILLIAMS ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 25, 38-40 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16-24, 26-37 and 41-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-12, 16-24, 26-37, and 41-49 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-15, 25, 38-40, and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

### ***Information Disclosure Statement***

Applicant is encouraged to file an information disclosure statement.

### ***Specification***

The disclosure is objected to because of the following informalities: The specification contains blanks on at least page 2.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least pages 10, 14, and 18.

### ***Claim Rejections - 35 USC § 101***

Claims 1-12 and 16-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Art Unit: 1631

Claims 1-12 are directed to a method for analysis comprising the steps of aligning sequences and determining whether clusters need to be modified. These steps as written are limited to data manipulation and do not result in a tangible, concrete, and useful result. As such, these claims are considered to be non-statutory. See MPEP 2106.

Claims 16-24 are directed to a method for designing a nucleic acid probe array comprising aligning sequences, modifying clusters, and selecting probes. The steps as written are limited to data manipulation and do not result in a tangible, concrete, and useful result. No step provides the nucleic acid probe array design of the preamble. Note that while the probes selected are targeted to a cluster the claim does not indicate that the cluster has any tangible, concrete, or useful application. As such, these claims are considered to be non-statutory. See MPEP 2106.

***Claim Rejections - 35 USC § 112***

Claims 1-12, 16-24, 26-37, and 41-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-12 are directed to a method for analyzing a plurality of transcript sequences in a cluster. The method as written does not provide sufficient positive, active steps to practice the method. At least for example, the claim does not require clustering the sequences in a particular way. There is no guidance on how to determine whether the clusters need to be modified. The claims and specification provide no criteria by which such a determination is made and what

Art Unit: 1631

type of modification to make. With respect to how to use, the claims and specification fail to tell how to use any and all information that results from the method as written in a real world application.

Claims 16-24 are directed to a method for designing a nucleic acid probe array. The method as written does not provide sufficient positive, active steps to practice the method. At least for example, the claim does not have any design steps nor results in a design for a nucleic acid probe array. There is no guidance on how to determine whether the clusters need to be modified. The claims and specification provide no criteria by which such a determination is made and what type of modification to make. The claims and specification provide no criteria by which the probes are selected. With respect to how to use, the claims and specification fail to tell how to use any and all information that results from the method as written in a real world application.

Claims 26-37 and 41-49 are directed to a computer readable medium comprising computer executable code to perform a method. As set forth above, the methods as written do not provide sufficient positive, active steps to practice the methods. As such, one would not be able to produce computer executable code to perform the methods as written nor would one know what to do the results of such a method when executed.

Claims 1-12, 16-24, 26-37 and 41-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1631

The preamble of claim 1 recites "sequences in a cluster." However, the body of the claim does not require that the sequences be clustered in any way. That is, there is no step for clustering the sequences such that the determination of the second step may be performed.

Claim 1 recites "modified according to the aligning." However, the claim is incomplete and confusing as it does not provide any criteria by which the determination is made. In addition, the metes and bounds of "modified" is not known. The claim does not make clear what type of modification is to be made, what would demonstrate a need for such modification, nor does it require that such modification occur. See also claim 26.

Claim 7 is confusing. While claim 2 (upon which it depends) comprises classifying as a chimeric cluster, it does not appear to require identifying multiple clusters or saving such information such that any chimeric cluster could be subclustered. It appears that the **sequences** within the cluster are realigned. Furthermore, claim 2 does not require that a chimeric cluster be found. If no clusters have been classified as chimeric, it is unclear how to proceed in claim 7. See also claim 32.

Claim 16 is directed to a method of designing a nucleic acid probe array. The final step is selecting probes. Selection of probes does not result in a design for a nucleic acid probe array. The claims are incomplete as the steps recited do not provide the stated goal of the preamble.

Claim 16 is also confusing in reciting "modifying the clusters according to their aligning to the genomic sequence to obtain at least one modified cluster." This does not set forth the positive, active steps that must be taken. It is not known what the metes and bounds of "modifying" are. The recitation "according to their aligning" does not indicate the criteria by

Art Unit: 1631

which the need for modification is decided nor the type of modification to be made. See also claim 41.

Claim 17 is confusing in reciting "chimeric clusters." Claim 16 lacks antecedent basis for this phrase. See also claim 42.

Claim 18 recites that a cluster is classified. It is unclear if this classification is a positive, active step of the method or merely a descriptive characterization of the cluster. It appears that claim 16 may have been intended to include a step to identifying chimeric clusters according to the criteria of claim 18. See also claim 43.

Claim 36 is confusing in being dependent upon non-elected claim 25. It appears that this dependency may be a typographical error.

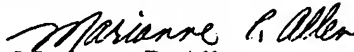
Claims 26 and 41 are confusing in reciting "performing the method comprising." It is unclear what the intended goal of the method is.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa